6385 '02 MAR 26 P2:20

MAR 13 2002

Mr. Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Road
Bloomingdale, Illinois 60108

Dear Mr. Roza:

This is in response to your letter of December 12, 2001 to the Food and Drug
Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal
Food, Drug, and Cosmetic Act (the Act)).

The product **Total Maintenance** uses the claim "...supports healthy blood glucose
levels." In the preamble to the January 6, 2000 final rule on structure/function claims
(see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal
cholesterol levels did not necessarily constitute implied disease claims. We stated,
however, that because "many people think of cholesterol solely in terms of the negative
role of elevated cholesterol in heart disease," in order to avoid implying that the product
prevents or treats heart disease, a cholesterol maintenance claim would have to clarify
that the product is only for maintenance of cholesterol levels that are already within the
normal range. The same principle applies to your claim about control of blood sugar
level; that is, a claim that does not establish that the claim is about blood sugar that is
already within normal limits implies that the product is intended to treat elevated blood
sugar or diabetes, which is a disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority
of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific
disease or class of diseases. The statement that you are making for this product suggests
that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the
requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for
use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to
regulation under the drug provisions of the Act. If you intend to make claims of this
nature, you should contact FDA's Center for Drug Evaluation and Research (CDER),
Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
  and Dietary Supplements
Center for Food Safety
  and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Chicago District Office, Office of Compliance, HFR-MW140

RE [...]
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BY: ....
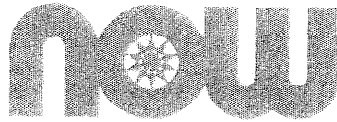
December 12, 2001

Office of Special Nutritionals (HF-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of
nutritional support in the labeling of Total Maintenance, a dietary supplement.

Statements being made in the labeling of Total Maintenance

(1)   Total Maintenance is an organic kosher herbal supplement designed to support the
healthy functioning of important body systems. Fenugreek, Garlic and Olive Leaf
are popular herbs used for centuries by many different cultures. Vitamins C and E
are effective antioxidants that support immune system function. Chromium is an
important mineral that supports healthy blood glucose levels. Together these
nutrients form a synergistic supplement that can be used year-round.

To the best of my knowledge, and based upon information and belief present at the time
of the executing of this notice, I certify that the above information is accurate and
complete. NOW Foods possesses substantiation that the statements are truthful and not
misleading.

Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Rd.
Bloomingdale, IL 60108

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